

Exhibit F



Deposition of:
David Kessler , M.D.

July 31, 2017

In the Matter of:
**In Re: Bard IVC Filters Products
Liability**

Veritext Legal Solutions

1075 Peachtree St. NE , Suite 3625

Atlanta, GA, 30309

800.808.4958 | calendar-atl@veritext.com | 770.343.9696

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1 request -- I was on the board of AsoThera. I am no
2 longer on that board for about a year. It changed its
3 name to Stoke.

4 Q Have you left any board of directors that are
5 listed on your C.V. since that time?

6 A Yes, Tokai was sold, and that was -- it was in
7 actually a merger, an inverted merger with Tokai.

8 Q Any other boards that you've left since that
9 time?

10 A No.

11 Q Do you still maintain your board certification in
12 pediatrics?

13 A No, I have not.

14 Q When did that lapse?

15 A I think I -- I don't think it was on here. It
16 was several years ago. I decided not to -- I have to do
17 my certification -- my recertification. I just -- I
18 have not done that. I have to go check. It was several
19 years ago.

20 Q And you are not board-certified in any field of
21 medicine now?

22 A That's correct. I'm licensed, but I'm not
23 board-certified.

24 Q Have you practiced, actually treated patients
25 since October of last year?

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1 than what's on the website.

2 Q Have you taken any affirmative steps to
3 investigate that other than to check the website?

4 A I've checked the website and I believe I've
5 checked the record. I think I've searched the record
6 for that.

7 Q Have you made any calls to anyone else?

8 A No, I've not made any calls. I've checked the
9 record and I've checked the public -- the public
10 website, the public information.

11 Q We talked earlier about depositions and trial
12 testimony that you've given since October of last year.
13 Have you submitted any new written reports in
14 pharmaceutical or medical device litigation other than
15 the reports you have submitted supplemental reports in
16 the Bard litigation and the report you submitted in the
17 Cook litigation?

18 A I may have submitted a report in the Texas A.G.
19 case.

20 Q Any other cases that you've submitted reports in
21 2017 or since October of '16?

22 A That's the one that comes to mind. And I don't
23 know -- I don't have the dates, sir, of when that was.

24 Q At the last time we met in October of 2016, you
25 had not billed the plaintiffs and did not know how much

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1 time you had spent. Subsequent to that deposition, we
2 received from Mr. Lopez a copy of an invoice you had
3 submitted soon after the deposition for roughly 500,000,
4 a little more than 500,000.

5 A Yes, I saw that this morning.

6 Q Now, you have spent additional time in this
7 litigation since submitting that invoice in October of
8 last year, correct?

9 A I think there's a second invoice if I'm correct.

10 Q Do you have that with you today?

11 A I think I asked Counsel to pull all invoices.

12 MR. NORTH: I think it's coming to me. Thank
13 you, sir.

14 (Exhibit 9 was marked for identification
15 by the court reporter and is attached hereto.)

16 BY MR. NORTH:

17 Q We have marked as Exhibit 9 the invoices that
18 Counsel just provided me. And there are two invoices
19 there, correct?

20 A Yes.

21 Q One of those invoices is the one we referenced in
22 October of last year for 596,000 and some change,
23 correct?

24 A Correct.

25 Q And then another one is from March of this year.

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1 And that -- what's the exact date on that?

2 A March 20th, sir.

3 Q March 20th?

4 A Yes, sir.

5 Q And that invoice is for \$26,000?

6 A Yes.

7 Q And looking back at your first supplemental
8 report, that was signed and dated March 3rd of 2017,
9 correct?

10 A Correct.

11 Q And so the March 20th of 2017 invoice would have
12 covered the time that you spent on that report, correct?

13 A Correct.

14 Q And so that time was charged in accordance with
15 your normal rate at \$1,000 an hour?

16 A Correct.

17 Q So you spent 26 hours in preparing the
18 supplemental report that we have identified as Exhibit 3
19 here?

20 A That was the amount -- that was what I spent,
21 yes. I mean, there may been work done in that first
22 500-plus that went into that second, but the actual
23 preparation of the report.

24 Q Have you not billed the plaintiffs since
25 March 20th of 2017?

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1 not intend to offer opinions regarding Bard's knowledge
2 or state of mind; is that still correct?

3 MR. ARBITBLIT: Objection. Compound. You need
4 to clarify that.

5 THE DEPONENT: I certainly will not want -- I
6 will not discuss state of mind. Knowledge is a
7 complicated matter. I would not talk about what
8 knowledge there is in anyone's head. I would only do it
9 on the basis of objective evidence of what a company
10 stated or a company did in documents.

11 BY MR. NORTH:

12 Q You do not intend to offer opinions regarding the
13 FDA's state of mind, do you?

14 A We discussed that last time. My answer as a
15 whole is I'm not sure how many one even does that. The
16 answer is obviously not.

17 Q Do you intend to offer opinions regarding Bard's
18 ethics?

19 A Not in those terms, but I will tell you that I
20 have some increasing concerns about Bard's conduct in
21 its carrying out of the clinical trial Everest. And so
22 the answer is not ethics but the propriety of how it
23 conducted that clinical trial I have serious concerns
24 about. But not in the ethical -- well, I'll leave
25 others to talk about ethics, whether -- I'm not going to

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1 talk about ethics, but I have, again, considerable
2 concern even since we talked last.

3 Q Which of the Bard filters had clinical studies
4 performed by Bard?

5 A So there's a -- there is a -- I think it's fair
6 to say there's a debate on if you look at Dr. Asch's
7 work whether that was a clinical study or not, whether
8 there was a protocol. He wrote it up. There was some
9 post hoc documents after the written -- again, I'm happy
10 to discuss that. So there is Asch. There is Everest.
11 Again, with regard to retrievability, both Asch, Everest
12 and Denali are the ones that I focused on. Again, I
13 reserve the clinical studies. I think Asch was --
14 again, was arguable whether it's a clinical study or
15 not.

16 Q You in your original report about -- or you
17 mentioned that there were a number of reports with
18 regard to the recovery filter of a cephalad migration of
19 the filter to the heart leading to death, correct?

20 A Yes.

21 Q Are you aware of any single report of a cephalad
22 migration of a G2 filter leading to death in a patient?

23 A I have searched the database for that, and as you
24 know, I have a list of -- in the schedule I list all
25 deaths associated, and there are deaths associated with

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1 Q You're not a vascular surgeon?

2 A That's correct.

3 Q You're not a cardiologist?

4 A I've been trained -- I've obviously been trained
5 in those kind of disciplines, not to the degree that
6 those individuals are.

7 Q You're not a member of the Society of
8 Interventional Radiologists, are you?

9 A I am not.

10 Q Have you ever attended one of their meetings or
11 conferences?

12 A I have no recollection of ever doing that.

13 Q Do you read the journal, their JVR journal?

14 A I certainly have read that journal and I look at
15 it when I search PubMed if it's relevant to what I'm
16 searching for.

17 Q But do you subscribe to it?

18 A My library subscribes to it.

19 Q Do you routinely read it on a monthly basis?

20 A No, I do not.

21 Q Are you a member of the Society of Vascular
22 Surgeons?

23 A No.

24 Q Have you ever treated a patient with regard to an
25 IVC filter in any fashion?

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1 A I have no recollection. I may have. I just
2 don't have a recollection.

3 Q But you've certainly never implanted one?

4 A That's correct.

5 Q And you've not explanted one?

6 A That's correct.

7 Q Have you ever seen an IVC filter implanted,
8 observed the procedure?

9 THE REPORTER: Implant what?

10 BY MR. NORTH:

11 Q Implanted. Have you ever observed a procedure?

12 A I don't have a recollection. There's not a
13 memory of that per se. I've certainly been in the IR
14 suites when I was running a hospital, but I'd have to
15 refresh my memory.

16 Q Have you ever observed a procedure where an IVC
17 filter was explanted?

18 A I don't believe so.

19 Q Have you ever, as part of treating a patient, had
20 to make a decision as to which sort of IVC filter to
21 recommend for that patient?

22 A No.

23 Q Have you ever participated on hospital committees
24 that decided what IVC filter a hospital should purchase?

25 A I was chair of PAT committee for a good nine

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1 Q And if in reviewing a 510(k) application the FDA
2 wants the label changed, it can request it, correct?

3 A It's part of a negotiation with the company.
4 There's a back and forth.

5 Q And, in fact, for the G2 -- G2 filter, the FDA
6 requested a warning -- specific warning regarding the
7 use of the filter in morbidly obese patients, correct?

8 A I'd have to go back. I think there was a
9 request. I'd have to go back and actually understand
10 that chronology with regard to morbidly obese. I do
11 have it in my notes here.

12 Q Do you recall one way or the other whether a
13 warning regarding morbidly obese patients was ultimately
14 added to the G2 IFU?

15 A I have it here in my schedules exactly. Just let
16 me be -- I believe so. Happy to check. Just give me a
17 second and I can be double sure. Let me just see if I
18 can... I'd have to double-check on that to be sure. I
19 believe that's correct. But I think that there was a
20 back and forth with the company.

21 Q You haven't spoken with any of the actual
22 reviewers of Bard's 510(k)s, have you?

23 A I have not. I stayed with the record.

24 Q Are you going to offer any opinions that Bard, in
25 designing, manufacturing and selling any of its IVC

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1 filters, broke the law or violated the law in any way?

2 A That's a legal opinion. I'm not going to give a
3 legal opinion. I do talk about the device not meeting
4 certain standards, and that being -- falling below
5 either an industry standard or adulteration, or what a
6 reasonably prudent manufacturer, but I will stay in
7 those kind of contexts of adulteration, what a
8 reasonably prudent manufacturer would do. I mean, but
9 ultimate legal questions I'll leave to the jury.

10 Q Would you agree that with regard to Bard's IVC
11 filters, the FDA requested more follow-up information
12 than it sometimes does with other devices?

13 MR. ARBITBLIT: Object to form.

14 THE DEPONENT: No. Well, in the abstract, it did
15 what it does in a 510(k) for an implantable device.

16 BY MR. NORTH:

17 Q Well, there are some implant -- some situations
18 where the FDA doesn't ask follow-up questions, correct?

19 MR. ARBITBLIT: Object to form.

20 THE DEPONENT: I rarely see FDA doesn't have some
21 follow-up questions.

22 BY MR. NORTH:

23 Q Well, my recollection -- and you were involved in
24 the pelvic mesh -- pelvic mesh MDL. My recollection is
25 that the agent -- the company submitted the 510(k) for

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1 DH -- design history file. But it is thousands of
2 pages. I would have to go back and look at the IDE,
3 whether the IDE is part of the design history file.

4 Q Have you reviewed any correspondence from the FDA
5 to Bard regarding the Denali study?

6 A I would have to go -- I would have to go back. I
7 think there is a production on Denali that I have looked
8 at. I think if my memory serves me right there wasn't a
9 production on Meridian, but I think there is a
10 production on FDA that I had at one point looked at,
11 yes.

12 Q Did the Denali study have any secondary
13 influence?

14 A I am sure it did. I would have to pull it.

15 Q Do you know what those are?

16 A I have it here if you want me to look at it. I'd
17 have to pull the final study report. Happy to do that,
18 but it will take me a couple of minutes. It is not here
19 in the -- I just don't have it in front of me.

20 Q Do you know off the top of your head whether the
21 FDA reviewed data regarding the secondary influence of
22 the study before clearing the Denali?

23 A Again, I'd have to go back and look. I know the
24 final study report wasn't done. I don't know exactly
25 how much data was in there. Certainly you would look at

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1 both the primary and secondary end points. But again,
2 it wasn't as -- it was a retrievability study. Hold on
3 one second.

4 Q Do you know whether there was an agreement
5 between FDA and Bard as to what point in the progress of
6 the Denali study they needed to be at before Bard would
7 submit the 510(k)?

8 A Hold on. I think I can probably find information
9 on that if you give me a couple of minutes. I have it
10 here.

11 Q Again, Doctor, I am asking you what you know and
12 recall.

13 A I am not going to sit here -- it's not what I
14 researched. There are -- there are thousands and
15 thousands of points. I don't recall exactly what was
16 stated, but I do have the documentation if you want to
17 give me a couple of minutes to look at it. In fact, if
18 you have it, why don't you just give it to me?

19 Q I don't have it.

20 A Okay. Well, I'd be happy to get it. I'd be
21 happy to pull up the DHA.

22 Q Do you know if the FDA asked questions of Bard
23 after it submitted its 510(k) about the Denali data?

24 A I would certainly expect it to.

25 Q Do you recall specifically as you sit here

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1 whether it did?

2 A I do not. I would have to go back and look. But
3 I would expect it to have.

4 Q Now your report contains a lot of criticisms of
5 the migration resistance test for the recovery filter,
6 correct?

7 A No. I have -- that's not what my report -- I
8 don't think that would be a fair reading of my report.
9 My report talks about the failure of that test by
10 recovery and falling below the standard and Bard's
11 handling of that.

12 Q But didn't you criticize the specification for
13 migration resistance itself?

14 A I know --

15 Q The 50 -- what is it MMHG?

16 A That was in Bard's -- Bard set that. That is
17 not -- I mean, Bard set that as a performance test.
18 That is different than the actual methodology. It came
19 up with -- that was its performance standard when it
20 knew that filters would be subject to greater standards.
21 So it was what Bard did with the test and how it set the
22 test that is the problem.

23 MR. NORTH: Move to strike as nonresponsive.

24 BY MR. NORTH:

25 Q Did you or did you not criticize the selection of

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1 that criteria for the test?

2 A Yes. That's different than -- that's the
3 specifications that Bard set. It didn't have to set
4 that. I certainly criticized that because Bard knew the
5 pressures were greater in the sheep studies than the 35
6 that the 50 was based on.

7 Q Do you know if that same standard was used for
8 the Eclipse?

9 A So my understanding -- I would have to go back
10 and look at the Eclipse again. At that point they were
11 dealing with caudal migration testing. And it was a
12 different test scenario that I think was at issue with
13 regard to Eclipse, right? Issues with caudal migration,
14 not the kind of migration resistance that they were
15 dealing with in recovery.

16 Q Do you know whether that same specification for
17 the test was utilized for the Meridian or the Denali?

18 A I would have to -- for caudal migration or the
19 recovery?

20 Q The same specification you criticized, the 50
21 MMHG.

22 A I'd have to go back and look at Meridian and see
23 what's in -- see what's in there. I do not know that as
24 I sit here.

25 Q Do you intend to offer any opinions as to whether

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1 the design of one or more of Bard's retrievable filters
2 were defective?

3 A Not as an ultimate legal matter as in terms of
4 design defect. But certainly as the medical monitor
5 said, you know, he thought it should be redesigned.
6 Certainly when it failed it was adulterated. So in
7 essence it should never have -- you know, it shouldn't
8 have been -- seen the market or been left on the market
9 because of its -- because it failed those tests. That's
10 what I will testify to. So but it goes to adulteration
11 and the industry standard not a question of ultimately
12 whether there was a -- the legal question of the design
13 defect.

14 Q Well, it's outside the range of your particular
15 focus and area of expertise to, for example, try to come
16 up with alternative designs for the device, correct?

17 A That's not -- I issued no opinions on that.

18 Q Is it your opinion that the recovery filter was
19 unsafe --

20 A But certainly Bard, in essence, did that. Bard
21 knew, you know, that there was migration at -- or very
22 early on in the G2 and knew what fixes had to take
23 place. And you don't see those anchors really coming
24 into play until years later in Meridian and Denali.
25 So -- but what my report deals with are -- the fixes

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1 were well articulated by Bard in its documents. And so
2 I am happy to talk about those design changes that Bard
3 said needed to be made that were not made in the device.
4 Even the -- what is striking is Bard was redesigning its
5 G2 and still letting the medical monitor, you know, that
6 trial go ahead.

7 MR. NORTH: Move to strike as non-responsive.

8 BY MR. NORTH:

9 Q Do you believe the Denali is unsafe?

10 A I have no opinion on that. And I don't -- let me
11 say, I don't think that there is a study that exists
12 that shows the risks are acceptable in light of the
13 benefits for Denali. I don't think that study was ever
14 done.

15 Q Do you have an opinion as to what specific aspect
16 of the design of the Bard filters may lead to fracture?

17 MR. ARBITBLIT: Object to form.

18 THE DEPONENT: Which filter are we talking about?

19 BY MR. NORTH:

20 Q Of the Bard filters.

21 MR. ARBITBLIT: Object to form.

22 BY MR. NORTH:

23 Q Any of them.

24 A Just state your question one more time.

25 Q Do you have any opinion as to the specific aspect

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1 of the design that may lead to fracture in any of the
2 Bard filters?

3 A So certainly what you can see in the record, that
4 there is this intersection between -- well, this is
5 probably the best chart, about fracture tilt,
6 penetration and migration. So I do have a view that
7 these things are related and connected.

8 MR. NORTH: Move to strike as nonresponsive.

9 BY MR. NORTH:

10 Q My question was do you have an opinion as to what
11 specific aspect of the design of the filters may lead to
12 fracture.

13 MR. ARBITBLIT: Object to form.

14 THE DEPONENT: Yes. I think I answered your
15 question. Just -- so when -- if something is going to
16 tilt or something is going to penetrate or something is
17 going to migrate, right, it is connected to the assure
18 fracture and puts additional stress on these devices.
19 If you go back and look at the Everest data, there are
20 certain correlations between these type of devices.
21 And, in fact, if you look at the complaint analysis,
22 right, for both Everest and for the adverse events, you
23 see those -- those interconnection of those -- those
24 reports. So put a tilt, perforate, migrate and that
25 will be related to make this correlation with fracture.

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1 MR. NORTH: Move to strike as nonresponsive.

2 BY MR. NORTH:

3 Q I am not asking about the interplay of various
4 complication modes. The question has nothing to do with
5 that. My question is do you have an opinion as to what
6 specific aspect of the design, what physical aspect of
7 the design of this filter -- these filters may lead to
8 fracture.

9 MR. ARBITBLIT: Object to form.

10 THE DEPONENT: So without, for example, the kind
11 of stability that the SNF had, without the kind of
12 anchoring that Bard did sort of late in the 2000s,
13 that's going to leave a filter in a more unstable state
14 and lead to these interplay of factors that have an
15 effect on fracture.

16 MR. NORTH: Move to strike as nonresponsive.

17 BY MR. NORTH:

18 Q Have you ever personally conducted an animal
19 study?

20 A Sure.

21 Q In what context?

22 A Certainly I did many animal studies in my
23 training, my medical school training.

24 Q Can you give me one example?

25 A Sure. I mean, this was bone grafts, cartilage

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1 grafts, rabbit studies, amphibian studies. I did many
2 animal studies and certainly reviewed animal studies
3 many times as -- in my role in FDA.

4 Q You criticized that performance specification for
5 the migration resistance testing. Do you have an
6 opinion as to what the proper performance specification
7 should have been?

8 A I think that Bard basically -- I am not going to
9 give an opinion, but when you see Bard moving later on
10 to '80, you can see what -- I am not going to give you a
11 specific opinion and a specific number, but certainly
12 Bard moved it up, realized it had to be moved up.

13 Q But you're not stating your own opinion as to
14 what it should have been?

15 A I am certainly stating 50 -- it could not be 50
16 because there were pressures applied that were greater
17 than 50. And obviously 50, setting it at 50 resulted in
18 these devices failing.

19 Q But you have not reached an opinion as to what
20 number in excess of 50 it should have been?

21 A No. No, but as I said before, Bard moved it up
22 to 80. I have no opinion of whether -- I am not issuing
23 an opinion of whether that was adequate, but I do note
24 that for the record.

25 Q That migration resistance test that you are

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1 referring to, did it measure resistance to cephalad and
2 caudal migration or only one distance, one direction?

3 A It was not specifically set up, as I remember,
4 for caudal when it was done. That was a separate test
5 that came around 2006. I would have to go -- I would
6 have to go back and look at exactly how they set up the
7 sheeps in order to answer that, but it was certainly a
8 separate test on caudal.

9 Q So the tests that you -- sorry. To be sure that
10 record is clear, the test that you are criticizing the
11 specification for, the 50 MMHG, that was a test designed
12 to test resistance to cephalad migration?

13 A I don't think that was the way that the
14 investigators set it up. I think they looked at it in
15 terms of general migration. This issue of caudal
16 migration was an issue that saw the light of day in the
17 middle of G2. So I would have to go back and we'd
18 probably have to go ask the investigators how they
19 viewed the original migration test.

20 Q Do you know whether the 50 MMHG standard was the
21 standard that the test expected all -- strike that. Do
22 you know whether that was an absolute migration
23 resistance value or a mean migration resistance value?

24 A I would have to go pull the actual performance
25 standard. You have both individual filters failing and

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1 then in certain tests with regard to recovery it was the
2 mean. So either way the device failed. I would have to
3 look and see exactly the way the end point was set, the
4 actual wording of it. I mean, I have some recollection
5 about mean, but I wouldn't want to -- I would have to --
6 we would have to pull up those clinical study reports,
7 but it failed even under the mean.

8 Q Now, you also have a criticism of an early MMT
9 technical report regarding the leg span, correct?

10 A There is, yes. There is -- well, you say early.
11 This is late 1990s. But you saw that the device didn't
12 hook in with those shorter leg spans. And you couldn't
13 assure any resistance to migration unless it was
14 specifically hooked in. The conclusion was those
15 shorter leg spans were the problem.

16 Q Are you aware of any report of the Bard recovery
17 filter migrating in the cephalad direction that was due
18 to the filter failing to initially engage the wall of
19 the IVC?

20 A We don't know that.

21 Q Are you aware of any report of a cephalad --
22 report of a cephalad migration with the recovery filter
23 that happened at the time of the deployment?

24 A I don't. I would have to go back and look or
25 subsequently, I mean, it could happen subsequent to it.

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1 Q Do you believe the recovery filter was
2 adulterated?

3 A Sure.

4 Q What's your basis for that?

5 A It failed to meet the quality standard that was
6 set.

7 Q You believe it was misbranded?

8 A Certainly there were statements made that were
9 misleading, which, again, is an ultimate -- there were
10 misleading statements, claims that were made about
11 recovery.

12 Q Do you believe that rose to the level of
13 misbranded?

14 A Yes. It was certainly misleading, yes.

15 Q That is misleading. I am asking misbranded.

16 A So, again, let me see what I actually -- I used
17 the word "adulterated." Let me just make sure. Let me
18 just double-check something. Let me check the hard
19 copy. So I think I used in my report that there were
20 statements that were misleading. And let me leave it at
21 that in my report.

22 BY MR. NORTH:

23 Q So you are saying that there are statements that
24 are misleading, but you are not willing to say one way
25 or the other whether that rose to the level of being

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1 Q My question is what is your basis for saying that
2 the Eclipse or giving an opinion that the Eclipse is
3 adulterated if you do not even know as you sit here
4 whether the Eclipse had a higher or lower migration rate
5 than the G2?

6 MR. ARBITBLIT: Object to form.

7 THE DEPONENT: I said -- I believe I said if you
8 had looked back at the transcript the company with
9 regard to Eclipse failed to ensure the safety. Because
10 you didn't put -- you didn't strengthen the anchors with
11 regard to Eclipse. You didn't do that until Meridian.
12 Your client didn't do that until Meridian. It didn't
13 fix the problem that it had seen. It knew that that was
14 an issue and didn't address it. In fact it only did it
15 by electropolishing.

16 BY MR. NORTH:

17 Q I understand you looked at data that means you
18 conclude that was an issue with regard to G2. But you
19 haven't seen data that has indicated one way or the
20 other whether that was an issue with Eclipse, did you?

21 MR. ARBITBLIT: Object to form.

22 THE DEPONENT: Same filter. I just told you it
23 was in the top five complaints. Right here if you look
24 at BPV filter 28-00117980 it is in the top five
25 complaints, and yet it was not addressed to Meridian.